3-24-99

DOCKETS MANAGEMENT BRANCH (HFA-305)
FOOD AND DRUG ADMINISTRATION
5630 FISHERS LANE ROOM 1061
ROCKVILLE MD 20852
Docket No. 98N1265
FDADockets@bangat.fda.gov

FDA:

As a consumer of healthcare services, I wish to register my objections to 99 APR 13 AM 10:22
provisions of the Memorandum of Understanding (MOU) as published by the FDA on January 21, 1999. I thank the Food and Drug Administration for making it possible to purchase prescription products individually compounded for my needs. I also appreciate the option of using products made from natural ingredients as opposed to patented synthetics. Unfortunately, the restrictions the MOU places on compounding pharmacies have the effect of denying many consumers the option of using these valuable products, and the potential to jeopardize my right to buy the products I choose from the pharmacists my doctor and I trust most.

Specific sections of concern include all of section MOU II-C and all of III-C: Distribution of inordinate Amounts of Compounded Drugs. These sections can, by placing restrictions on the amounts that can be sold out of state, discriminate against consumers who do not live in the state where the products preferred by their physicians are compounded. Economically, they discriminate against health-care consumers who cannot afford to travel and obtain care in the state where their preferred compounding pharmacy is located.

By threatening the economic survival of pharmacies whose superior products draw physicians and customers from out of state, the MOU threatens to make the superior products unavailable to consumers who need them. Doing so would unfairly restrict consumer choice. Federal restrictions in place effectively deny these products to the vast majority of consumers. Section II-B of the MOU refers to restrictions on a compounding pharmacy's right to promote its products and services. The result is that most consumers don't know they exist, and the only physicians who know about them are the enlightened physicians who take the initiative to seek them out. By contrast, FDA does not prevent manufacturers of patented, synthetic, one-size-fits-all preparations from large-scale advertising designed to persuade consumers to tell their physicians to prescribe their drugs. often in spite of a nightmare litany of side effects, adverse reactions, and contraindications. FDA allows advertising of OTC drugs available even to children without a prescription.

Please amend the memorandum of understanding to avoid jeopardizing my right to buy products compounded for my needs anywhere I choose in the United States. I want no restrictions to delivery of a compounded medication prescribed for me, regardless of where I may live or travel. Thank you!

Signed:
Address:

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